



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,122	11/12/2003	Jurgen Brinkhues	9003-286US	6214
570	7590	02/14/2008	EXAMINER	
PANITCH SCHWARZE BELISARIO & NADEL LLP			MEHTA, BHISMA	
ONE COMMERCE SQUARE			ART UNIT	PAPER NUMBER
2005 MARKET STREET, SUITE 2200				3767
PHILADELPHIA, PA 19103			MAIL DATE	DELIVERY MODE
			02/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,122	Applicant(s) BRINKHUES, JURGEN
	Examiner BHISMA MEHTA	Art Unit 3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 November 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 15-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/DS/02)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claim Objections

1. Claims 15-20 are objected to because of the following informalities: There appears to be text missing between "working" and "the" in line 18 of claim 15. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 15, 16, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawlikowski (U.S. Patent No. 4,929,231) in view of Pharma Gummi Wimmer West GmbH (EP 0 148 426) ("Pharma Gummi"). In Figure 1, Pawlikowski shows a piston stopper comprising a base body (28) with a displacement transferring element (24) and a piston section (34). The piston section in a working position faces the contents of a syringe or carpule cylinder (10). The outer circumference of the piston section (34) abuts against the syringe or carpule cylinder (10). The piston stopper has an uncoated sealing section adjacent to the piston section (34) and which abuts flat against the syringe or carpule cylinder (10). At least one continuous sealing lip (at 28 in Figure 1) is provided on the outer circumference of the sealing section. On an outer circumference of the sealing section, there is an annular continuous sealing zone which

is directly adjacent to and directly adjoining to an edge region of the piston section (34) and which abuts against an inner wall of the syringe or carpule cylinder. At least a portion of the sealing zone is provided as a straight extension to the edge of the piston section (34) such that the sealing zone is aligned with a surface of the piston section (34) so that in the working position, the piston stopper abuts the sealing section fully against the syringe or carpule cylinder. Pawlikowski discloses the piston stopper substantially as claimed. Even though Pawlikowski discloses a portion of the base body being made from an elastomer (lines 35-40 of column 2), Pawlikowski is silent on the base body (28) being made substantially from an elastomer and being made in one piece. Also, even though Pawlikowski discloses that the displacement transferring section is integral with the base body, Pawlikowski is silent on the specifics of the base body (28) comprising a receiving cavity. Pawlikowski is also silent on the piston section (34) being enclosed in a cap-shaped inert film and where the film comprises a fluorinated polymer film. In Figure 18, Pharma Gummi shows a rubber piston stopper (33) having multiple sealing lips (34, 35, 36) and a receiving cavity where a cross-section of the receiving cavity tapers out toward an opening of the receiving cavity. In lines 1-10 of page 2, Pharma Gummi discloses the piston stopper as being made essentially or substantially from an elastomer such as rubber. As shown in Figure 18, the base body of the piston stopper is made in one piece. In lines 3-10 of page 29, Pharma Gummi teach enclosing a piston section (37) of the piston stopper in a cap-shaped inert film (8) comprising a fluorinated polymer film. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the

Art Unit: 3767

base body of Pawlikowski substantially from an elastomer and in one piece as taught by Pharma Gummi as both Pawlikowski and Pharma Gummi disclose an elastomer such as rubber as being a suitable material for a piston stopper and Pharma Gummi teaches that it is well known to make the base body in one piece made substantially from an elastomer. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to provide the piston stopper of Pawlikowski with a receiving cavity as taught by Pharma Gummi as Pharma Gummi provides a receiving cavity on the piston stopper which can be used to connect to a displacement transferring element (similar to that shown in Figure 17 of Pharma Gummi). It would have been obvious to one having ordinary skill in the art at the time the invention was made to enclose the piston section of Pawlikowski in a cap-shaped inert film such as a fluorinated polymer film as taught by Pharma Gummi as Pharma Gummi teach that it is well known to provide an inert film on a piston section of a piston stopper which is facing the contents of a syringe cylinder to avoid unwanted interaction between the contents of the syringe cylinder and the rubber portion of the piston stopper (see line 16 of page 8 to line 10 of page 9).

4. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawlikowski in view of Pharma Gummi as applied to claim 15 above, and further in view of McConnaughey (U.S. Patent 2,895,773). Pawlikowski and Pharma Gummi disclose the piston stopper substantially as claimed. However, Pawlikowski and Pharma Gummi are silent to a section of an inside wall of the piston stopper bordering the receiving cavity having an internal thread to connect with a thread of the

displacement transferring element. In Figure 3, McConnaughey show a section of an inside wall of the piston stopper with an internal thread (304b) to connect with a thread (322b) of a displacement transferring element (320) where the internal thread (304b) terminates at a spacing from a bottom (306) of the receiving cavity (310). The section with the internal thread (304b) terminates at the piston section (302a) or at a spacing from it and a cylindrical or tapered receiving cavity (at 321c in Figure 3a) extends between the internal thread (304b) and the section of the receiving cavity (310) which extends into the piston section (302a). As seen in Figure 3a, a cross-section of the receiving cavity (310) tapers out from the bottom (306) of the receiving cavity toward an opening of the receiving cavity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a section of an inside wall of the piston stopper bordering the receiving cavity of Pharma Gummi with an internal thread to connect with a thread of the displacement transferring element as taught by McConnaughey as McConnaughey teaches that it is well known to connect a piston stopper with a displacement transferring element using threads.

Response to Arguments

5. Applicant's arguments filed November 2 2008 have been fully considered but they are not persuasive. Applicant's remarks in lines 20-21 of page 6 are unclear because the syringe of Pharma Gummi has not been disclosed as being reusable. Applicant's arguments in lines 7-18 of page 7 and in line 27 of page 7 to line 16 of page 8 that Pawlikowski and Pharma Gummi would not be combined by one having ordinary

skill in the art as indicated above in the prior art rejection are not persuasive. In lines 22-25 of page 10, Pharma Gummi teaches using a very thin layer of the fluorinated polymer film and, therefore, enclosing the piston section (34) of Pawlikowski with a very thin layer of the fluorinated polymer film would still allow the piston section (34) to deform within the conical surface and would also prevent unwanted interaction between the contents of the syringe and the piston stopper. Furthermore, in lines 7-10 of page 9 of Pharma Gummi, it is indicated that the polymer film extends only over a small part of the stopper and, this combined with the teaching of a very thin layer of the polymer film would result in a comparatively slight increase in the cost of the syringe of Pawlikowski. This slight increase in the cost of the syringe would be insignificant when considering the advantages of providing an inert film as indicated by Pharma Gummi in lines 1-15 of page 3. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Pharma Gummi clearly teaches that it is well known to provide an inert film on a piston section of the piston stopper to eliminate the problem of incompatibility between the piston stopper and the contents of the syringe (lines 1-4 of page 4). In response to applicant's argument in lines 19-26 of page 7 that Pawlikowski teaches away from enclosing the

piston section in an inert film because "typical prior art hypodermic syringes" are reusable and the syringe of Pharma Gummi is this type of "prior art hypodermic syringe", there is no evidence that the syringe of Pharma Gummi can be considered reusable. Applicant's connection between "typical prior art hypodermic syringes" and the syringe of Pharma Gummi being reusable is unclear and without basis. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 3767

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767